REMARKS/ARGUMENT

Claims 51-59 were pending prior to this amendment.

Claims 51-55 and 56-59 are rejected as obvious under 35 USC 103 over Pathak (US 6,113,944) in combination with Benneker (US 5,874,447) and Takedo (US 5,486,365).

Claim 56-58 are rejected under 35 USC 112 due to confusion in the claims over the lower limit of the water content.

Claim 56 is amended.

Claims 51-59 are presented for reconsideration.

The present invention, as currently claimed in claims 51-55 is a lactose and microcrystalline cellulose free formulation of a paroxetine sulfonate salt (inclusive of paroxetine methane sulfonate) in combination with calcium hydrogen phosphate anhydrate and a disintegrant and a lubricant. The invention claimed in claims 56-59 is a coposition of a sulfonate salt of paroxetine (inclusive of paroxetine methane sulfonate) in combination with calcium hydrogen phosphate anhydrate, a disintegrant, and a lubricant, where the added water content is not over 1.2% and the pH is from 5.0 to 6.0. In claims 56-59 neither lactose or microcrystalline cellulose are excluded.

The Examiner should note that each of the claims requires that the paroxetine be in the form of a sulfonate salt thereof (inclusive of paroxetine methane sulfonate) and the formulation contain calcium hydrogen phosphate anhydrate. As set forth at page 8 of the present specification, these two components make it possible to prepare paroxetine formulations that are stable and do not discolor. These two components are also responsible, rather surprisingly, for

the ability to prepare paroxetine formulations in which the biter taste of paroxetine is overcome without the use of taste masking agents.

The Examiner has rejected claims 56-58 due to confusion over the lower limit of water content. Specifically, claim 56 recited merely a "water content of 1.2%", while dependent claims 57 and 58 recited a water content range from 0% up to an amount that was less than 1.2%. Applicant wished to thank the Examiner for pointing out the discrepancy and indicating the phrase "or less" was apparently left out of claim 56 based on the specification. As such, Applicant has amended claim 56 to include the phrase "or less". Thus as amended, claims 56-58 now overcome the 35 USC 112 rejection and that ground for rejection should now be withdrawn.

The Examiner also rejected all of the claims over the combination of three references; namely, Pathak (US 6,113,944), Benneker (US 5,874,447), and Takado (US 5,486,3565). It is the Examiner's position that it would be obvious to modify the Pathak disclosure by replacing the paroxetine hydrochloride therein with paroxetine methane sulfonate (from Benneker) and replacing the calcium phosphate therein with calcium hydrogen phosphate anhydrate (from Takado) to arrive at the invention claimed in claims 51-55 and that further modification of the pH would be of routine optimization to arrive at the claim 56-59 invention.

Applicant acknowledges that Pathak shows a dry granulation of paroxetine hydrochloride with dicalcium phosphate, sodium starch glycollate (disintegrant), and magnesium stearate (lubricant) both in the presence and absence of microcrystalline cellulose, and in the absence of lactose. The examiner's stated position omits the fact that the Pathak invention is that microcrystalline cellulose is discussed as "particularly good results are obtained when microcrystalline cellulose is absent from the formulation" and "this is surprising as tablets formulated in the absence of microcrystalline cellulose are often prone to breaking up during manufacture or storage". Note also that the claims do not require the omission of the microcrystalline cellulose. Thus, according to Pathak, it is for the specific formulation therein that microcrystalline cellulose is optionally present or absent. There is no true teaching that one

should expect this to carry over to products having different components as the physiochemical characteristics of different components are not the same. Thus, a combination of the three references as contended by the Examiner would not lead one clearly to the present invention, but would just as readily lead one to the inclusion of microcrystalline cellulose. Thus, on this ground, the combination does not lead one obviously to the claim 51-55 invention.

In addition, the Pathak reference uses dicalcium phosphate while the present invention (all claims0 require calcium hydrogen phosphate anhydrous. The Examiner contends that takado teaches that calcium hydrogen phosphate provides fluidity, increases stability, and decreases discoloration. The Examiner cites to Column 4, lines 10-23 for these properties, but that section of takado relates to vitamin C, a vary different molecule from paroxetine hydrochloride or paroxetine methanesulfonate (or any other sulfonate slat of paroxetine). The Examiner also points to column 7, lines 43-46, which merely is a generic statement that it has excellent binding properties and can be used in medicines. None of these statements teaches or suggests tone of ordinary skill that they should expect success in achieving the results of the invention by replacing the dicalcium phosphate of Pathak with calcium hydrogen phosphate anhydrate. At most, the reference might teach that it would be a good suggestion to try the calcium hydrogen phosphate anhydrate, but a suggestion to try without an expectation of success is insufficient for a prima facie case of obviousness. Thus, the rejection is overcome on this basis alone and should be withdrawn.

Still further, as indicated on page 8 of the present specification, the calcium hydrogen phosphate anhydrate component of the present invention surprisingly results in a paroxetine which no longer has the bitter taste that is characteristic of paroxetine per se, its slats and most formulations thereof. Thus, this surprising result permits one to prepare formulations for oral consumption that do not need to have separate taste masking agents of need to be encapsulated or film coated, thereby resulting in substantially cheaper manufacturing costs. None of the references mention, teach, or suggest such an unexpected and surprising result. Thus, even if the Examiner's assertion to combine the three references in the manner set forth were to be sufficient

for a prima facie case (which Applicant contends it is not), then the existence of this surprising and unexpected result is itself sufficient to overcome such prima facie case. As such, the instant rejections of claims 51-55 and 56-59 are overcome and the claims as currently presented are allowable.

As such, a Notice of Allowance is respectfully requested.

Respectfully submitted,

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